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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,377

08/26/2008

Alan Rory Mor McLeod

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11/16/2011

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EXAMINER

ECKMAN, MICHELLE

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

11/16/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,377	Applicant(s) MCLEOD ET AL.	
	Examiner MICHELLE C. ECKMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-9, 11-25 and 28-30 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-9, 11-25 and 28-30 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/29/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Lines 1-2 of claim 15 recite “the one or more fibrous filling elements act to space the fibrous filling elements apart from each other”. It is unclear how one or more fibrous filling elements act to space fibrous filling elements. Claim 15, is misdescriptive. As best understood by the specification, there are two fibers of two different fibers (small and large) and the smaller fibers are positioned between the larger fibers (see Fig. 7 and para. [0106]).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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1. Claims 1-4, 19-20 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (U.S. Patent 5,702,454, hereinafter "Baumgartner").

Baumgartner discloses regarding claim 1, a spinal implant, comprising: a porous component (i.e. woven fabric bag, see lines 20-37 of column 4); and one or more fibrous filling elements (Ref. 20 or 22, Figs. 6 and 8; see also lines 22-25 of column 5 and lines 39-44 of column 5, note "string-like" see definition <http://www.thefreedictionary.com/string-like> note "made of fiber") provided within the porous component.

Regarding claim 2, the implant is at least one of a partial nucleus pulposus replacement and a total nucleus replacement (see lines 49-53 of column 1).

Regarding claim 3, in which the porous component is a container having an opening to permit the insertion of the one or more fibrous filling elements (see lines 58-67 of column 2 and lines 20-37 of column 4).

Regarding claim 4, in which the porous container is made of fabric (see lines 20-37 of column 4).

Regarding claim 19, the one or more fibrous filling elements are provided with pieces (Ref. 7, see Figs. 6 and 8) provided therein, the pieces being intermixed with the one or more fibrous filling elements.

Regarding claim 20, the pieces are at least one of spheres, beads, and blocks (see Figs. 6 and 8).

Regarding claim 25, a method for performing spine surgery for partial replacement of a nucleus of an intervertebral disc, comprising: gaining access to the

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nucleus through an incision; removing at least part of the nucleus to create a space (see lines 49-53 of column 1); inserting an implant into the space, the implant including an outer component manufactured at least in part of fabric and reduced to a small size to allow insertion into the space without enlarging the incision (see lines 20-37 of column 4); and inserting at least one fibrous filling element into the outer component during surgery to expand the outer component (see lines 58-67 of column 2 and lines 20-37 of column 4).

2. Claims 1-6, 11-25, 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich (U.S. 2005/0055094 A1, hereinafter "Kuslich").

Kuslich discloses regarding claim 1, a spinal implant, comprising: a porous component (18); and one or more fibrous filling elements (20) provided within the porous component.

Regarding claim 2, the implant is at least one of a partial nucleus pulposus replacement and a total nucleus replacement (see para. [0039]).

Regarding claim 3, in which the porous component is a container having an opening to permit the insertion of the one or more fibrous filling elements (see para. [0038]).

Regarding claim 4, in which the porous container is made of fabric (see para. [0038]).

Regarding claim 5, in which the porous component is configured with pores having at least one cross-sectional dimension that is less than a smallest cross-sectional dimension of the fibrous filling elements (see para. [0038] "contains", the

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examiner notes that if the cross-sectional dimension of the pores in the porous component were not smaller than the smallest cross-sectional dimension of the fibrous filling elements that the fibrous filling elements would not be contained inside the porous component).

Regarding claim 6, the porous component is at least one of configured, formed of and provided with one or more materials intended to promote tissue growth, particularly tissue ingrowth through at least one of the porous component and between the porous component and one or more of the filling elements and between two or more of the fibrous filling elements (see para. [0038], “fabric or other porous shell 18”, a fabric would be configured to promote tissue growth into the device; see also para. [0036] “induces living, natural fibrous tissue growth”).

Regarding claim 11, the one or more fibrous filling elements are provided as at least one of porous defining voids within themselves and defining voids between parts of the one or more fibrous filling elements element (see annotated Fig. 5 below).

Regarding claim 12, the one or more fibrous filling elements are formed of at least one of unconstrained fibers, unbraided fibers, and interlaced fibers (see annotated Fig. 5 below).

Regarding claim 13, the one or more fibrous filling elements are provided with aligned fibers (see annotated Fig. 5 below).

Regarding claim 14, the one or more fibrous filling elements are provided as at least one of for instance wavy, curved, and zig-zag fibers (see annotated Fig. 5 below).

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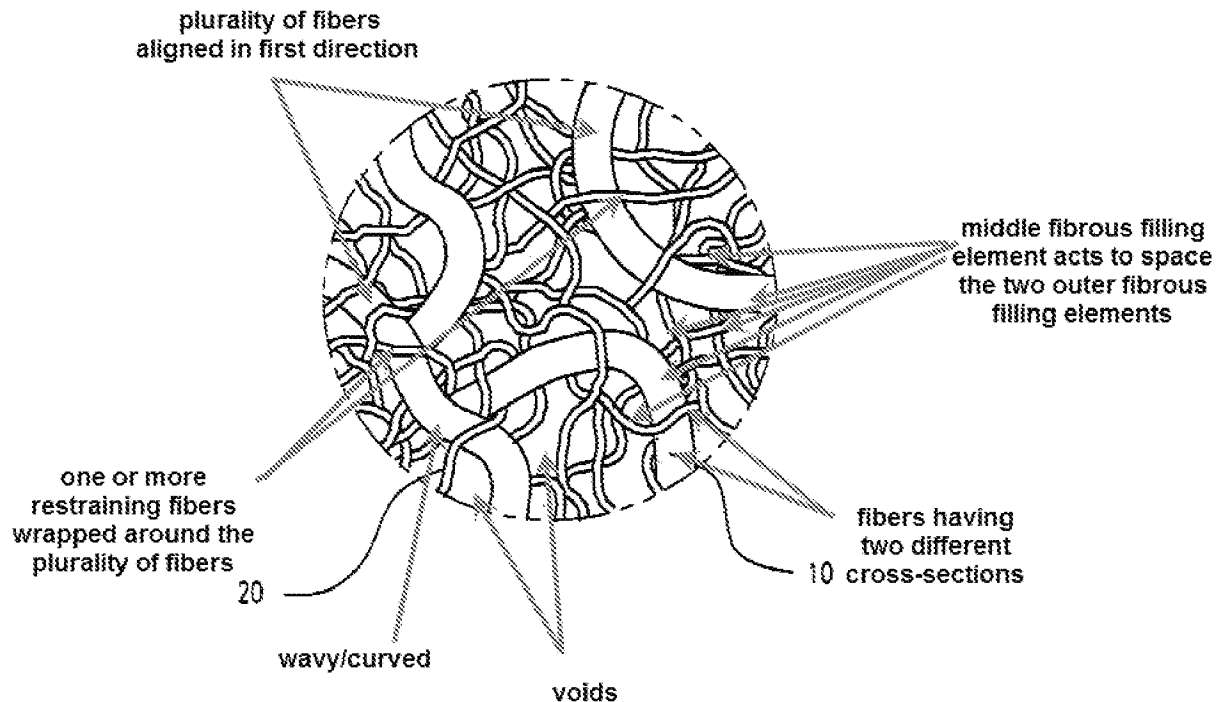
Regarding claim 15, the one or more fibrous filling elements act to space the fibrous filling elements apart from each other (see annotated Fig. 5 below).

Regarding claim 16, the one or more fibrous filling elements are provided with fibers having two or more different cross sections (see annotated Fig. 5 below).

Regarding claim 17, the one or more fibrous filling elements are provided as a plurality of fibers aligned in a first direction are provided, with one or more restraining fibers which are wrapped around the plurality of fibers (see annotated Fig. 5 below).

Regarding claim 18, the plurality of fibers are provided with peripheral fibers which are wrapped around the plurality of fibers in at least one of a spiral manner and a criss-cross manner (see annotated Fig. 5 below).

FIG. 5



Regarding claim 21, the fibrous filling elements are configured with at least one of pores, voids, apertures, and gaps occurring in the fibrous filling elements that are due to at least one of the manner of manufacture of the fibrous filling element, and supplementation with further pores, voids, apertures, and gaps (see paras. [0034] and [0036], note that the fibers contain pharmaceuticals and minerals that would be absorbed by the growing tissues leaving voids in the fibers).

Regarding claim 22, the one or more fibrous filling elements are formed with at least one of one or more materials intended to promote tissue growth, particularly tissue ingrowth through at least one of the one or more fibrous filling elements between the

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porous component and one or more filling elements and between two or more of the fibrous filling elements (see paras. [0034] and [0036]).

Regarding claim 23, the one or more materials used in one or more of the fibrous filling elements are bio-absorbable and the bio-absorbable material is used to decrease over time at least one of the amount of one or more fibrous filling elements present, and positions at which one or more fibrous filling elements is present and density at which the one or more fibrous filling elements is present (see paras. [0034] and [0036]).

Regarding claim 24, the bio-absorbable material restrains one or more of the fibrous filling elements, in a first state, the bio-absorption of the material allowing the one or more fibrous filling elements to assume a second state, the second state providing at least one of a greater internal volume for the one or more fibrous filling elements and greater porosity for the one or more fibrous filling elements reduction in mass of the one or more fibrous filling elements to provide more space for tissue ingrowth (see paras. [0034] and [0036], note that the fibrous tissue inducers will be absorbed by the tissue in growth and will provide more space for tissue ingrowth).

Regarding claim 25, a method for performing spine surgery for partial replacement of a nucleus of an intervertebral disc, comprising: gaining access to the nucleus through an incision (see para. [0039]); removing at least part of the nucleus to create a space (see para. [0039]); inserting an implant into the space, the implant including an outer component manufactured at least in part of fabric (18) and reduced to a small size to allow insertion into the space without enlarging the incision (see para.

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[0038]); and inserting at least one fibrous filling element (20) into the outer component during surgery to expand the outer component (see paras. [0036] and [0040]).

Regarding claim 28, in which the method includes a first time in which the implant provides at least one characteristic of a naturally occurring disc by virtue of a non-biological mechanism, and a second time at which the implant provides at least one characteristic of a naturally occurring disc by a combination of a non-biological mechanism and biological mechanism (see paras. [0036] and [0034], note that fibrous filling elements (20) provides stability and cushioning to mimic the spine, also note that the fibrous filling elements contain pharmaceuticals and minerals to promote tissue ingrowth and will be absorbed by the tissue ingrowth).

Regarding claim 29, the method includes a third time with substantially all of the one or more characteristics of a naturally occurring disc are provided by a biological mechanism (see paras. [0036] and [0034], note that the pharmaceuticals and minerals will be absorbed by the tissue ingrowth and replaced by natural tissue).

Regarding claim 30, the transition from the mechanism at the first time to the second time is due to bio-absorption of one or more of the materials forming the implant and particularly forming the one or more fibrous filling elements (see paras. [0034] and [0036], note that the pharmaceuticals and minerals will be absorbed by the tissue ingrowth).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Pub. No. 2005/0055094 A1, hereinafter "Kuslich"), as applied to claim 1 above, in view of McLeod et al. (U.S. Patent 6,093,205, hereinafter "McLeod").

Kuslich discloses all of the features of the claimed invention, as previously set forth above, except for: wherein one or more materials used in the porous component is bio-absorbable, as per claim 7; the bio-absorbable material is used to decrease over time at least one of the amount of porous component present, positions at which the porous component is present, and density at which the porous component is present, as per claim 8; and the bio-absorbable material restrains the porous component in a first state, the bio-absorption of the material allowing the porous component to assume a second state, as per claim 9.

McLeod teaches making a fabric material that surrounds a spinal implant out of a material that is bio-absorbable in order to enable tissue ingrowth and disc regrowth (see lines 19-22 of column 3 and lines 22-30 of column 6).

It would have been obvious to one having ordinary skill in the art to at the time the invention was made to include a bio-absorbable material into the porous component in Kuslich in view of McLeod in order to better enable tissue ingrowth and disc regrowth. And further, it would have been obvious to one having ordinary skill in the art at the time the invention was made include bio-absorbable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of

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its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 8/29/2011 have been fully considered but they are not persuasive.

Applicant asserts that Baumgartner does not appear to disclose the limitation of a fibrous filling element as required by amended claim 1. The examiner respectfully disagrees, Baumgartner discloses that the support members (7) can be connected by string-like support (20). See definition of "string-like"

<http://www.thefreedictionary.com/string-like>, note that a string-like support would be "made of fiber" and therefore fibrous.

Applicant asserts that Baumgartner does not appear to disclose the limitation of inserting a fibrous filling element as required by amended claim 25. The examiner respectfully disagrees, Baumgartner discloses that the support members (7) can be connected by a string-like support (20).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892. McKay et al. (U.S. Pub. No. 2004/0059418 A1) discloses a porous component (272) filled with fibrous filling elements (276) (see paras. [0101]-[0103] and [0105]).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle C. Eckman whose telephone number is (571)270-7051. The examiner can normally be reached on Monday-Friday between 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Eduardo C. Robert, at (571) 272-4719***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. E./
Examiner, Art Unit 3733
/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733